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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,105	01/09/2002	Daniel J. Zyck	112703-212	9165

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,105

Applicant(s)

ZYCK ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 07/08/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 8, the phrase "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 10 is indefinite in that it refers to natural seaweeds, natural seed gums, natural plant exudates, and natural fiber extracts. While the terms themselves are not indefinite, it must be questioned whether artificial seaweeds, seed gums., plant exudates and fiber extracts exist which would be excluded by this terminology.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/682,164 ('164). Although the conflicting claims are not identical, they are not patentably distinct from each other because '164 claims an edible film for oral mucadhesion comprising maltodextrin and two other film forming agents which do not include pullulan. The '614 application includes the same fillers and hydrocolloids. Weight percentages for film forming agents are within the ranges claimed herein. The '164 reference differs only in that maltodextrin is one of the film forming agents in all its compositions. The instantly claimed film does include maltodextrin at claim 2. Therefore, it would have been well within the skill of the ordinary practitioner to claim the instant edible film comprising at least three types of film forming agents excluding pullulan given the claims of '164. Those of ordinary skill would have expected similar therapeutic results from the instantly claimed edible film given the claims of the '164. The instantly claimed edible film would therefore have been obvious given the claims of '164 which set out a similar film with at least three film forming agents.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al as applied to claims 1-20 above, and further in view of Meyers.

Zerbe et al teach a water-soluble composition for oral administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see column 2, lines 14-67; column 3, lines 1-61 and examples). Although Zerbe et al teaches a film composition comprising film-forming agents, filler and a plasticizer, the reference does not teach the particular film forming agent; maltodextrin. However, Zerbe et al does include a suggestion to use natural gums as the film forming agent (mucoadhesive film).

In another patent, Meyers teaches an edible film composition comprising film forming agents including maltodextrin, bulking agents, and plasticizers (see column 3, line 15 –col. 5, liner 15; col. 6, lines 20-38). Therefore, it would have been within the

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skill of one of ordinary skill in the art at the time of the invention was made to combine a film forming agent such as maltodextrin as taught by Meyers, in combination with the fillers and plasticizers of Zerbe. Meyers specifically teaches the use of an edible film composition comprising film-forming agents, such as maltodextrin, in combination with bulking agents and plasticizers. Therefore, those of ordinary skill would expect similar therapeutic results from the administration of the instant invention given the prior art which teaches the use of maltodextrin in film compositions also containing filler and plasticizer as shown by Zerbe in view of Meyers et al. The instant invention would have been obvious given the teachings of Zerbe et al which generally disclose the use of gums as film-forming agents in compositions also containing filler and plasticizer, and further in view of Meyers et al which specifically suggest the use of maltodextrin as the film forming agents of such oral film compositions.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwakura et al as applied to claims 1-20 above, and further in view of Meyers et al.

Iwakura et al teach a preparation in the form of a film for oral cavity administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see abstract; cols. 1-2). While Iwakura et al teaches a preparation in the form of a film-forming agent, filler and plasticizer, there is no teaching of the

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specific film-forming agent, maltodextrin. Iwakura et al does however disclose the use of natural gums as film forming agents (mucoadhesive film) at col. 2, lines 13-20.

In another patent, Meyers teaches an edible film composition comprising film forming agents including maltodextrin, bulking agents, and plasticizers (see column 3, line 15 –col. 5, liner 15; col. 6, lines 20-38). Therefore, it would have been within the skill of one of ordinary skill in the art at the time of the invention was made to combine a film forming agent such as maltodextrin as taught by Meyers, in combination with the fillers and plasticizers of Iwakura et al. Meyers specifically teaches the use of an edible film composition comprising film-forming agents, such as maltodextrin, in combination with bulking agents and plasticizers. Therefore, those of ordinary skill would expect similar therapeutic results from the administration of the instant invention given the prior art which teaches the use of maltodextrin in film compositions also containing filler and plasticizer as shown by Iwakura et al in view of Meyers et al. The instant invention would have been obvious given the teachings of Iwakura e et al which generally disclose the use of gums as film-forming agents in compositions also containing filler and plasticizer, and further in view of Meyers et al which specifically suggest the use of maltodextrin as the film forming agents of such oral film compositions.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Ca9
July 22, 2003



CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500